(c) by when Government propose to take a final decision in this regard?

THE MINISTER OF STATE IN THE DEPARTMENT OF CHEMICALS AND PETRO-CHEMICALS IN THE MINISTRY OF INDUSTRY (SHRI R. K. JAICHANDRA SINGH): (a) No, Sir.

(b) and (c) Do not arise.

Unauthorised production of medicines

1505. SHRI RAFIQUE ALAM: Will the Minister of INDUSTRY be pleased to state:

(a) whether it is a fact that the Hathi Committee recommended not to regularise unauthorised production of medicines;

(b) if so, what are the basis of such recommendations;

(c) whether it is also a fact that Drug Policy, 1978 does not permit regularisation of unauthorised production;

(d) whether it is a fact that his Ministry has proposed regularisation of unauthorised production;

(e) whether it is also a fact that majority of the formulations under unauthorised production are non-essential and useless;

(f) the names of the drug companies alongwith names of formulations of each company whose production was found of doubtful validity;

(g) name of the category under which each formulation falls;

(h) whether it is a fact that no case by case study has been made; and

(i) if so, what are the reasons for such regularisation in spite of prohibition by Hathi Committee?

THE MINISTER OF STATE IN THE DEPARTMENT OF CHEMICALS AND PETRO-CHEMICALS IN THE MINISTRY OF INDUSTRY (SHRI R. K. JAICHANDRA SINGH): (a) Yes, Sir.

(b) The report of the Hathi Committee was laid on the Table of the House and is available in the Parliament library which indicates details of its recommendations.

(c) The 1978 Drug Policy does not provide for regularisation of unauthorised production.

(d) The series of measures announced by the Government in December, 1986 provide for regularisation of such production.

(e) No, Sir.

(f) Information is given in Annexure [*See* Appendix CXLII, annexure No. 73].

(g) Items of doubtful validity can be classified into the following groups:

(1) Items claimed to be covered under Registration Certificates issued under Section 10 of the I(D&R) Act.

(2) Items claimed under exemptions from industrial licensing but in respect of which no COB licences were obtained after the said exemptions were withdrawn.

(3) Items with a composition different from that already authorised and hence amounting to manufacture of new articles.

(4) Items not covered by any approval under the I(D&R) Act.

(h) and (i) An Inter-Ministerial Working Group was set up in 1982 to examine the question of production of drugs with valid approval and to suggest possible lines of action that may be taken. Details of measures for regularisation, quality control and growth of pharmaceutical industry in India giving rational of each of the decision have already been laid on the Table of the House in reply to various questions and are also available in the library of the Parliament.